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No. 83-1932

In the Supreme Court of the United States

OCTOBER TERM, 1983

E. R. SQUIBB & SONS, INC.,

Petitioner,

vs.

THERESE MARIE COLLINS, et al.,

Respondents.

On Petition For A Writ Of Certiorari
To The Supreme Court Of Wisconsin

BRIEF OF RESPONDENT THERESE MARIE COLLINS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether a state's modification of its tort law to permit a rebuttable presumption of causation-in-fact under certain circumstances in an unusual class of personal injury cases violates the Due Process or Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution?

2. Whether a state-created rebuttable presumption of causation-in-fact in personal injury cases involving harm caused by the pregnancy drug DES violates the Supremacy Clause or the Interstate Commerce Clause of the United States Constitution?

TABLE OF CONTENTS

PAGE

QUESTIONS PRESENTED i

OPINION BELOW 1

STATEMENT OF THE CASE 2

REASONS FOR DENYING THE WRIT 5

I. The Collins decision does not deprive Petitioner of due process of law 6

A. The Collins decision does not deprive Petitioner of procedural due process 7

1. The Collins decision does not deprive Petitioner of substantive due process 7

2. As a rebuttable presumption of causation-in-fact, the Collins decision does not deprive Petitioner of procedural due process 8

B. The Collins decision does not deprive Petitioner of substantive due process 12

1. The Collins decision comes before this Court with a presumption of constitutionality for purposes of due-process review .. 12

2. The Collins decision rests upon a rational basis and is consistent with historical state tort law approaches to causation problems 13

II. The Collins decision does not deprive Petitioner of equal protection of the laws 16

A. The Collins decision comes before this Court with a presumption of constitutionality for purposes of equal-protection review 16

PAGE

B. The classifications drawn in the Collins decision are rationally related to a legitimate state interest 17

III. The state supreme court's application of the state constitution in the Collins decision to modify the state common law does not infringe on Petitioner's Fourteenth Amendment rights 19

IV. The Collins decision is not invalid under the Supremacy Clause 19

A. Federal law has not occupied the field of drug regulation so as to prevent states from supplementing the field 20

B. The Collins decision does not govern the same area as that of federal laws governing a drug manufacturer, nor does the Collins decision conflict with any federal statute 22

V. The Collins decision is not a regulation affecting interstate commerce 24

CONCLUSION 27

Appendix A

Footnote 25 from Joint Brief of Petitioner and the other defendant drug companies before the Wisconsin Supreme Court ..... App. 1

Appendix B

List of law review articles addressing the DES causation problem ..... App. 2

TABLE OF AUTHORITIES

Cases

PAGE

Abel v. Eli Lilly & Co., 418 Mich. 311, 343 N.W.2d 164 (1984) 5

Bichler v. Eli Lilly & Co., 55 N.Y.2d 571, 436 N.E.2d 182 (1982) 5

City of New Orleans v. Dukes, 427 U.S. 297 (1976) 16

Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919) 20

Easterling Lumber Co. v. Pierce, 235 U.S. 380 (1914) .. 8

Ferguson v. Skrupa, 372 U.S. 726 (1962) 13

Florida ex rel. Broward County v. Eli Lilly & Co., 329 F. Supp. 364 (S.D. Fla. 1971) 21

Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978) 5

Luria v. United States, 231 U.S. 9 (1913) 7

Lyons v. Premo Pharmaceutical Labs, Inc., 170 N.J. Super. 183, 406 A.2d 185 (1979) 5

McElhaney v. Eli Lilly & Co., 564 F. Supp. 265 (D. S.D. 1983) 5

Missouri, Kansas & Texas R. Co. v. Haber, 169 U.S. 613 (1898) 24, 25

Morton v. Abbott Laboratories, 538 F. Supp. 593 (M.D. Tex. 1982) 5

Orthopedic Equipment v. Eutsler, 276 F.2d 455 (4th Cir. 1960) 22

Payton v. Abbott Laboratories, 512 F. Supp. 1031 (D. Mass. 1981) 5

Ray v. Atlantic Richfield Co., 435 U.S. 151 (1978) 20

Ryan v. Eli Lilly & Co., 514 F. Supp. 1004 (D. S.C. 1981) 5

PAGE

Sherlock v. Alling, 93 U.S. 99 (1876) 24, 25

Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980) 3, 5, 15

62 Cases of Jam v. United States, 340 U.S. 593 (1951) 23

Southern R. Co. v. Railroad Commission, 236 U.S. 439 (1915) 22

Summers v. Tice, 33 Cal. 2d 80, 199 P.2d 1 (1948) 15

United States v. Carolene Products Co., 304 U.S. 144 (1938) 13

Usery v. Turner Elkhorn Mining Co., 428 U.S. 1 (1976) 8-12

Williamson v. Lee Optical Co., 348 U.S. 483 (1955) 13

Constitutional Provisions

United States Constitution, Article I, Section 8, Clause 3 24

United States Constitution, Article VI, Clause 2 19

United States Constitution, Fourteenth Amendment 6, 16

Statutes and Bills

Food, Drug and Cosmetic Act, 21 U.S.C. §301 23

Uniform Product Liability Bill, S. 44, 98th Cong., 1st Sess. (1983) 21

Other Authorities

Comment, Punitive Damages in DES Market Share Litigation, 23 Santa Clara L.Rev. 185 (1983) 6

Hearings on S. 1944, Before a Subcommittee of the Commerce Committee, U.S. Senate, 73d Cong., 2d Sess. (1933) 21

J. Wigmore, Evidence (3d ed. 1940) 7

Restatement, Second, Torts §433B(3) 15, 18

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The opinion of the Wisconsin Supreme Court is reported at 116 Wis.2d 166, 342 N.W.2d 37 (1984). The opinion is reproduced at pages 1-32 of the Appendix to the Petition ("Pet. App.-1-32").

STATEMENT OF THE CASE

We do not accept the statement of the case contained in the Petition. It is more appropriately categorized as an argument than as a statement of the case. For this reason, we present our own statement of the case.

Therese Marie Collins contracted cancer which necessitated the removal of her uterus, part of her vagina and a number of lymph nodes. As a result of the radical cancer surgery necessary to save her life, her bladder has ceased functioning. Pet. App.-2-3.

Ms. Collins filed suit against Petitioner and 16 other producers of the drug DES—the drug her mother took during pregnancy, and which she alleged resulted in the cancer from which Ms. Collins suffers. Before the trial court, Ms. Collins asserted that even though she could not pinpoint which drug company produced the pills her mother had taken, the trial court should modify the cause-in-fact requirement in Wisconsin in order to permit her to proceed with her case. The trial court refused, saying that such arguments were more appropriately addressed to the state supreme court. The Wisconsin Supreme Court undertook review, bypassing the intermediate appellate court.

The issue confronting the Wisconsin Supreme Court in the *Collins* case develops from the unusual circumstances that attend injury from DES consumption. The consumption of DES that gives rise to the injury occurs when the victim's *mother* ingests the drug while the mother is pregnant with the victim. The injurious consequences of DES consumption manifest themselves 10 to 20 years after the drug is consumed. This time gap makes it virtually impossible for most DES daughters to identify the manufacturer of the DES pills taken by their mothers.

Before the Wisconsin Supreme Court, Ms. Collins urged various modifications of the traditional cause-in-fact requirement, including market share liability among the defendants as announced in *Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980). Petitioner and the other defendant drug companies argued against any such modifications. The federal constitutional argument made by Petitioner and the other defendant drug companies for opposing the modification to the cause-in-fact rule was entirely contained in a two-sentence footnote in a 65-page brief before the state supreme court. The footnote is reproduced in full in Appendix A to this brief.

After examining the drug companies' arguments and the various modifications urged by Ms. Collins, the Wisconsin Supreme Court adopted its own rule concerning proof of causation-in-fact in DES situations, which rule, the court noted, also "could apply in situations which are factually similar to the DES cases." Pet. App.-18. The state supreme court's formulation created a rebuttable presumption of causation that attaches to any drug company defendant who produced DES. The presumption is based on the fact that each defendant who produced DES contributed to the risk of public injury, and, consequently, to the risk of individual injury that gave rise to the lawsuit. A defendant may rebut the presumption by showing that it was not the company that made the DES pills giving rise to the injury because it did not produce DES during the relevant time period, or did not market its DES in the relevant geographic area or in the physical form identified by the plaintiff. Pet. App.-18, 24-25. This allocation of proof in connection with the presumption is made because it is the defendant drug company, rather than the plaintiff, who has best access to knowledge of those facts.

Pet. App.-20. The alleged DES victim, however, still retains the burden of showing her injury in fact *was* caused by DES. The alternative to modifying traditional cause-in-fact allocations would be to deny the DES plaintiff any recovery whatever, where she cannot pinpoint the precise manufacturer of the DES pills which caused her injury.

The court's decision does not discuss the federal constitutional objections Petitioner mentioned in the two-sentence footnote contained in its state appellate brief. Petitioner and the other defendant drug companies sought reconsideration of the Wisconsin Supreme Court's decision. Pet. App.-33. The Wisconsin Supreme Court denied the motion for reconsideration without opinion. The case was remanded and is now proceeding in the state trial court. Petitioner has filed a summary judgment motion based on its assertion that its DES pills during the relevant time period were pink and did not match the description given by Ms. Collins' mother. *See* Pet. at 6. This summary judgment motion and that of other individual defendants who claim they can prove under the *Collins* decision that they did not produce the pills that caused Ms. Collins' injury are scheduled to be heard on July 9, 1984. Trial is scheduled for March 5, 1985.

REASONS FOR DENYING THE WRIT

Petitioner is the only one of 17 defendant drug companies to petition this Court to review the *Collins* decision of the Wisconsin Supreme Court, a decision which neither discusses nor states any principle of federal constitutional law. The *Collins* decision enunciates solely the policy of the state of Wisconsin. It is a policy with which Petitioner may disagree, but to which several of Wisconsin's sister states subscribe. *See Abel* v. *Eli Lilly & Co.*, 418 Mich. 311, 343 N.W.2d 164 (1984); *Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980); *McElhaney* v. *Eli Lilly & Co.*, 564 F. Supp. 265 (D. S.D. 1983); *Bichler* v. *Eli Lilly & Co.*, 55 N.Y.2d 571, 436 N.E. 2d 182 (1982). None of these decisions has discussed any federal constitutional dimension in their adaptation of the common law to meet the unusual issues presented by DES and similar cases. Other courts (all but one of them federal courts applying state law) have made different policy judgments and declined to adapt the local common law in this context, but none has done so on federal constitutional grounds. *See Morton* v. *Abbott Laboratories*, 538 F. Supp. 593 (M.D. Fla. 1982); *Ryan* v. *Eli Lilly & Co.*, 514 F. Supp. 1004 (D. S.C. 1981); *Payton* v. *Abbott Laboratories*, 512 F. Supp. 1031 (D. Mass. 1981); *Gray* v. *United States*, 445 F. Supp. 337 (S.D. Tex. 1978); *Lyons* v. *Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, 406 A.2d 185 (1979).

Further, numerous commentators have analyzed the issues attending DES litigation, but none has discerned federal constitutional problems with the types of adaptation

of common law that the *Collins* decision undertook.[1] The articles containing the commentators' analyses are listed in Appendix B to this Brief in Opposition. In short, then, neither courts nor commentators have found the approaches to causation involved in this and other DES cases to be constitutionally suspect.

Petitioner's position—that the *Collins* court's adaptation of common law is constitutionally suspect—is grounded in an expanded notion of the Constitution's reach, a notion that would reorder federal-state relations. In essence, Petitioner asks that, under the guise of interpreting the federal Constitution, this Court should not tolerate variances in state approaches to tort law. Because this is not a case where existing pronouncements of federal law must be reconciled—indeed, federal issues have never been addressed by the courts in the context of DES litigation—this Court should not undertake the review requested here.

I.

THE COLLINS DECISION DOES NOT DEPRIVE PETITIONER OF DUE PROCESS OF LAW.

The Fourteenth Amendment provides that "[n]o state shall . . . deprive any person of life, liberty, or property, without due process of law." This provision has been interpreted to provide both procedural and substantive safeguards.

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[1] The one commentator who discusses a federal constitutional issue in the context of DES litigation raises the question in connection with awards of punitive damages, an issue not present here. Comment, *Punitive Damages in DES Market Share Litigation*, 23 Santa Clara L. Rev. 185 (1983). Indeed, the Wisconsin Supreme Court in *Collins* specifically disallowed punitive damages in DES cases. Pet. App.-28-29.

A. The Collins Decision Does Not Deprive Petitioner Of Procedural Due Process.

Petitioner argues that the *Collins* decision creates a rule of evidence relating to causation that deprives it of procedural due process. Specifically, Petitioner claims that drug manufacturers who did not produce the DES tablets actually taken by Ms. Collins' mother may be improperly forced to share in the monetary liability of the company or companies that did produce the tablets.

Procedural due process is a flexible principle that must be adapted to each situation in order to balance the interests at stake. Although the due-process right to a hearing is generally found to embrace the right to present evidence, a state has considerable power to make or change rules that govern the introduction of evidence at trial to prove a particular issue. *Luria* v. *United States,* 231 U.S. 9 (1913). In fact, it is "evident that a right to have one's controversies determined by existing rules of evidence is not a vested right." 231 U.S. at 26.

1. The Collins Decision Does Not Create A Conclusive Presumption Of Causation.

A conclusive presumption is one which states a rule of substantive law. In contrast, a rebuttable presumption is a form of evidence that may be accepted when there is no other evidence to uphold the contention it supports, and may be rejected if it is overcome by other evidence. 9 J. Wigmore, *Evidence* §§2491, 2492 (3d ed. 1940).

Petitioner argues that the effect of the decision in *Collins* is to create a conclusive presumption that requires the trier of fact to find causation from the mere manufacture of DES. This characterization of the *Collins* ruling is inaccurate. The *Collins* formulation simply shifts the burden

of proof to the defendant drug manufacturers when the plaintiff cannot pinpoint which company manufactured the DES pills that her mother ingested.

There is, therefore, no substantive change in the law, but only a procedural change from which Petitioner has no constitutional right to be protected. *Easterling Lumber Co.* v. *Pierce,* 235 U.S. 380 (1914). Under the *Collins* rule, each defendant drug manufacturer may demonstrate that it did not make the pills that caused the plaintiff's injuries. Because each defendant is allowed to introduce such evidence, the decision can, at most, be interpreted as creating a rebuttable presumption of causation-in-fact. Indeed, the *Collins* decision goes to some length to detail what the rebutting evidence may be, including proof that the pills taken do not match the physical description of the defendant drug company's pills, that the company did not manufacture DES at the relevant time, or that it did not market DES in the relevant geographic area. Pet. App.-21, 24-25. Petitioner is simply incorrect when it states that the Wisconsin Supreme Court's decision offers no meaningful opportunity for a defendant drug manufacturer to exculpate itself.

2. As A Rebuttable Presumption Of Causation-In-Fact, The Collins Decision Does Not Deprive Petitioner Of Procedural Due Process.

In civil cases, procedural due process requires that rebuttable presumptions and allocations of the burden of proof satisfy the standard of "rationality." In a case involving statutory presumptions in a context markedly similar to the present one, this Court set out a standard for testing presumptions involving economic regulation of civil matters. *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976). The *Turner* case involved a Fifth Amendment due-process

challenge to certain evidentiary rules contained in the federal statute which provides a remedy to coal workers suffering from pneumonociosis (black lung disease). Under the statute, a coal mine operator is liable for death or total disability due to pneumonociosis contracted during employment in the operator's mine. Two coal mine operators challenged certain evidentiary rules designed to establish the element of causation. Despite due-process arguments almost identical to those advanced by Petitioner in this case, the *Turner* Court upheld the constitutionality of all the evidentiary presumptions in the federal statute.[2]

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[2] The major similarities between the *Turner* rebuttable presumption and the presumption as to causation in *Collins* are as follows:

(a) In *Turner*, the plaintiff coal miner or his survivors could shift the burden of proof for causation to the defendant coal mine operator by showing employment in the coal mines for a certain number of years. Under the *Collins* rule, a plaintiff DES daughter can shift the burden of proof for causation to the defendant drug companies by showing that she has joined in the action one or more potential manufacturers of the DES which her mother might have taken, with the opportunity available to that defendant to implead any additional such manufacturers.

(b) Like the defendants in *Turner*, the defendants in *Collins* have the opportunity to introduce evidence to show the lack of causation.

(c) Both the statute in *Turner* and the rule of *Collins* are cost-spreading devices which operate with less than perfect mathematical accuracy in individual cases. The statute in *Turner* could potentially hold a coal mine operator liable for pneumonociosis that was not contracted in his mines. Under the terms of the statute, a coal mine operator who cannot disprove causation can be held liable for death or disability benefits of a coal miner who contracted the disease while employed by a former employer or who never actually contracted the disease at all. Under the rule of *Collins*, a defendant drug man-

(footnote continued)

The Court in *Turner* articulated the standard it applied to determine whether the presumption was valid. The Court stated that "it is only essential that there shall be some rational connection between the fact proved and the ultimate facts presumed, and that the inference of one fact from proof of another shall not be so unreasonable as to be a purely arbitrary mandate." 428 U.S. at 28.

In *Collins*, the shifting of the burden of proof for causation is triggered by proof that (a) DES ingested by her mother caused the plaintiff's injuries, and (b) the plaintiff has joined one or more of the manufacturers of DES, which her mother ingested, with the manufacturers so joined entitled to implead any manufacturers who should have been joined but were not. There must be at least "some

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(footnote continued)

ufacturer who fails to show a lack of causation can be held liable for a proportion of the judgment even though it may not have manufactured the particular DES that was ingested by the plaintiff's mother.

The following are among the due process arguments that are common to Petitioner in this case and the defendants in *Turner*:

(a) The presumptions and limitations on rebuttal evidence unconstitutionally impair the defendant's ability to defend against the claims.

(b) The rules operate in an arbitrary and irrational manner by holding particular defendants liable for injuries they may not have actually caused.

(c) The rules will unfairly burden certain members of the industry.

(d) The rules create an improper method of cost spreading.

(e) The facts triggering the operation of presumptions are arbitrary (*i.e.*, in *Turner*, a 10 or 15-year period of working in the mines; in this case, sales of DES in the relevant geographic area during the relevant time period).

rational connection'' between proof that those manufacturers have been joined and the presumption that one of the defendants so joined is actually responsible for the plaintiff's injuries, and that all are responsible for the risk to the public occasioned by the marketing of DES.

In light of this Court's holding in *Turner*, the *Collins* presumption operates in a rational way. A presumption that one of several defendants caused an injury is not any more ''arbitrary'' or ''irrational'' than a presumption that a miner died due to pneumonociosis (based on proof that he worked in the mines for ten years and dies of a ''respirable disease''). In fact, the possibility of error under the *Collins* rule is actually smaller than that under the statute in *Turner*. Because the defendants in *Collins* are free to implead as many other manufacturers as they like, the possibility that none of the defendants before the court caused the plaintiff's injury can virtually be eliminated. Each of the defendants, of course, is responsible for creating the public risk that is manifest in the individual plaintiff: the production and marketing of a harmful drug having a chemical constituency identical to that of each of its competitors' pills.

The *Turner* case does not require that the rules of law relating to causation match liability and actual responsibility for injury with mathematical accuracy. Responding to the argument that the retroactive application of the statute creates the possibility that a coal mine operator may be held liable for injuries that he did not actually cause, the Court in *Turner* stated that ''the imposition of liability for effects and disabilities bred in the past is justified as a rational measure to spread the costs of the employee's disabilities to those who have profited from the fruits of their labor—the operators and the coal consumers. . . .'' 428 U.S. at 18. The *Collins* decision does not prevent Peti-

tioner or any other possible defendant from presenting its evidence that *its* DES pills were not the ones ingested by Therese Collins' mother. Under the *Turner* analysis, this is more than is necessary to sustain the *Collins* presumption as rational, and therefore not violative of Petitioner's procedural due process rights.

B. The Collins Decision Does Not Deprive Petitioner Of Substantive Due Process.

Under the presumption established in *Collins*, each defendant who fails to demonstrate that it did not make the pills that caused the plaintiff's injuries is held liable for a portion of the judgment on a comparative negligence basis. Petitioner claims that this presumption and apportionment of judgment among the defendants is arbitrary and irrational and, as a result, deprives it of substantive due process. This is incorrect.

1. The Collins Decision Comes Before This Court With A Presumption Of Constitutionality For Purposes Of Due-Process Review.

The *Collins* decision creates a rule of law affecting the economic and social welfare of the citizenry of Wisconsin. The rule is designed to provide a remedy for injuries suffered by innocent persons caused by a harmful product, and to spread the costs of such injuries among the manufacturers who profited from its production.

When a rule of law which adjusts the benefits and burdens of economic life for social welfare reasons is challenged before this Court, the rule is presumed to be constitutional. The burden is on the one complaining to establish that the rule operates in an arbitrary and irrational manner. *Usery* v. *Turner Elkhorn Mining Company*, 428

U.S. 1 (1976); *Ferguson* v. *Skrupa*, 372 U.S. 726 (1962); *Williamson* v. *Lee Optical Co.*, 348 U.S. 483, 487-88 (1955); *United States* v. *Carolene Products Co.*, 304 U.S. 144, 148 (1938).

2. The Collins Decision Rests Upon A Rational Basis And Is Consistent With Historic State Tort Law Approaches To Causation Problems.

The standard for testing the due-process constitutionality of a rule of law regulating economic relationships and social welfare was specified in *United States* v. *Carolene Products Co.*, 304 U.S. 144 (1938). In that case, Justice Stone stated:

> "Regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in light of the facts made known and generally assumed it is of such a character as to preclude the assumption that it rests upon some *rational basis* within the knowledge and experience of the legislators." 304 U.S. at 152 (emphasis added).

The Wisconsin Supreme Court's thorough discussion of the problem it faced in *Collins* and its resolution of that problem, makes it clear that there is a rational basis for the rebuttable presumption established in the decision. Specifically, the problem arises from the DES plaintiff's inability to identify which drug company or companies manufactured the actual DES pills ingested by the plaintiff's mother. The Wisconsin Supreme Court resolves the dilemma by putting the burden on the defendant drug company to demonstrate that it did not market DES at the time or in the geographic market or in the form in which the drug was ingested. This preserves rather than eliminates the defendant drug company's existing defenses, and places the burden to overcome the presumption in the

hands of the party most likely to have information as to whether it may have contributed to the risk—the manufacturer of the drug. It is in fact the manufacturer even more so than the doctor prescribing DES (the only logical alternative defendant a plaintiff could turn to if she cannot join the manufacturer) who has the best access to information about its own marketing history.

The Wisconsin Supreme Court decided that division of liability by comparative negligence among all manufacturing drug companies who put the public at risk was the best method of compensating the innocent victims of DES, while fairly protecting the property interests of the defendant drug manufacturers. In so concluding, the state court recognized that the facts before it made it *impossible* to create a rule that exactly matched liability with actual responsibility for injury. At the extremes, the court was faced with either denying relief to DES daughters who cannot identify the manufacturer of the DES pills their mothers ingested or holding undiluted joint and several liability against the drug manufacturers. Refusing to accept either extreme, the Wisconsin Supreme Court fashioned a rule of law that militates the inequities of both extremes. The court adopted a rule of law that will allow damages to be apportioned according to the comparative culpability among the defendants whose actions put the public health at risk, and who cannot demonstrate that they did not cause the plaintiff's injuries. Surely it is *not* irrational for a court to provide a remedy that protects the interests of both the plaintiff and the defendants in a tort case.

The Wisconsin Supreme Court's resolution is consistent with time-honored allocations of proof and presumption in state tort law throughout this country. Perhaps the clearest analogy in tort law is to those cases that hold inde-

pendent tortfeasors jointly and severally liable for a plaintiff's injuries where neither the plaintiff nor the defendants can identify the particular tortfeasor who actually caused the plaintiff's injuries. Under these doctrines, there is potential for a 100% error in matching liability with actual responsibility for the harm (*i.e.*, a single innocent defendant can be held liable for 100% of the harm caused by another). The classic situation occurs where three defendants each negligently shoot a rifle in the plaintiff's direction, and the bullet from one rifle injures the plaintiff. Where neither the plaintiff nor the defendants know whose bullet struck the plaintiff, the defendants are jointly and severally liable for the injury. This is so even though it is clear that only one defendant's bullet caused the injury, and that the actual guilty defendant may be judgment-proof. Under the joint and several liability rules, the plaintiff may recover all of his damages from one or more defendants who are not actually guilty of causing the injury, thus creating a 100% error in matching liability with the actual cause of harm. This classic principle was first developed in *Summers* v. *Tice*, 33 Cal.2d 80, 199 P.2d 1 (1948), and is also embodied in the Restatement, Second, Torts §433B(3).

Thus, states other than Wisconsin also have acted within their traditional powers to regulate state tort law in making similar policy judgments in DES cases to allocate the burden of proof of causation-in-fact. *See, e.g., Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980). These policy judgments are appropriate functions for the states to undertake, and do not violate the due-process rights of drug manufacturers. Petitioner's request for this Court to substitute its judgment for that of a state supreme court would in effect alter the traditional roles of the state and federal judiciary.

II.

THE COLLINS DECISION DOES NOT DEPRIVE PETITIONER OF EQUAL PROTECTION OF THE LAWS.

The Fourteenth Amendment provides that "[n]o state shall . . . deny to any person within its jurisdiction the equal protection of the laws."

A. The Collins Decision Comes Before This Court With A Presumption Of Constitutionality For Purposes Of Equal Protection Review.

As discussed above, the *Collins* decision is a rule of law affecting the economic and social welfare of the citizenry of Wisconsin. The standards for reviewing rules affecting such matters under the Equal Protection Clause are similar to the standards for review under the Due Process Clause. The major difference is that the equal-protection review tests the rationality of the "classifications" drawn by the rule of law.

This Court, in *City of New Orleans* v. *Dukes*, 427 U.S. 297 (1976), noted that unless a classification trammels fundamental personal rights or is drawn upon inherently suspect distinctions such as race, religion, or alienage, this Court's decisions presume the constitutionality of the statutory discriminations. So long as the classification challenged is rationally related to a legitimate state interest, states are accorded wide latitude in the regulation of their local economies under their police powers. Moreover, the states' rational distinctions may be made with substantially less than mathematical exactitude. 427 U.S. at 303-04.

B. The Classifications Drawn In The Collins Decision Are Rationally Related To A Legitimate State Interest.

Petitioner argues that the *Collins* rule treats it differently than defendants in other tort cases. The classification, however, is not *DES manufacturers* versus all other defendants in tort cases, as Petitioner suggests. Rather, the Wisconsin Supreme Court noted that its adaptation of the causation element in tort cases would "apply in situations which are factually similar to the DES cases." Pet. App.-18. The classification thus applies in situations where manufacturers market a product that is harmful and actually causes harm, but because of the passage of time and the fungibility (i.e., identical chemical composition and appearance) of the various brands the victim cannot pinpoint which defendant manufactured the precise item that caused the harm (here, DES pills). This is appropriate, as noted earlier, because the manufacturers are in a better position than the victim to know where and when their products were marketed, and consequently whether their brand could have been one which caused the harm.

A state has a legitimate interest in compensating its citizens for injuries caused by dangerous products. The *Collins* formulation accommodates this interest by establishing a rebuttable presumption of causation-in-fact in limited circumstances that nevertheless extend beyond DES cases. This variation on usual causation rules is made for a simple common-sense reason. The rules are different because the circumstances of a DES daughter's injuries are different than the circumstances of the injuries in most tort cases.

Ms. Collins was injured by one of the many drug manufacturers that produced the identical drug using an identi-

cal formula. She cannot pinpoint exactly which among the manufacturers actually provided the product that caused her injuries because of the product's fungibility and the fact that it did not produce discoverable damage to her until almost 20 years after its purchase and ingestion by her mother.

The Wisconsin Supreme Court was faced with the difficult choice between denying compensation to plaintiffs like Ms. Collins or adapting its common law to the unusual circumstances of their injuries. The Wisconsin Supreme Court chose the latter alternative. Because the circumstances of Ms. Collins' injuries prevented her from identifying the particular tortfeasor who actually caused her harm, the Wisconsin Supreme Court had no choice but to depart from the rules generally used in tort cases to establish the element of causation. Such departures are not uncommon to Wisconsin and other states' law. As stated earlier, the Wisconsin Supreme Court and the courts of other states, as reflected in Section 433B(3) of the Second Restatement of Torts, have made exactly the same policy judgment. The *Collins* formulation is drawn so that it creates a potential for error that is actually smaller than that in the other "unidentified defendant" cases. Because the *Collins* rule reduces the potential for error and addresses the same circumstances as other well-established causation doctrines of state tort law, an equal-protection challenge to *Collins* can, necessarily, be no more persuasive than an equal-protection challenge to the Restatement of Torts.

III.

THE STATE SUPREME COURT'S APPLICATION OF THE STATE CONSTITUTION IN THE COLLINS DECISION TO MODIFY THE STATE COMMON LAW DOES NOT INFRINGE ON PETITIONER'S FOURTEENTH AMENDMENT RIGHTS.

The Wisconsin Supreme Court is, of course, the final authority on the meaning of the Wisconsin Constitution. That court's interpretation of the state constitution to permit the rebuttable presumption established in the *Collins* decision and used in considering the state law tort question raised there, is not subject to the federal revision Petitioner would like. Rather, the Wisconsin Supreme Court's interpretation and application of its own constitution may be overturned only if the state interpretation violates federal constitutional principles, which it does not do.

IV.

THE COLLINS DECISION IS NOT INVALID UNDER THE SUPREMACY CLAUSE.

The Supremacy Clause of the United States Constitution provides that the "Constitution and the laws of the United States which shall be made in pursuance thereof; and all Treaties made or which shall be made under the authority of the United States shall be the supreme law of the land . . . ." Article VI, Clause 2. Thus, to the extent that Congress has exercised one of its powers, any inconsistent state law is prohibited. It is unclear precisely what aspects of federal policy or law Petitioner claims are frustrated or interfered with in the *Collins* decision. We will, therefore, address each of the possible Supremacy Clause

elements that have been identified as subject to analysis in this Court's treatment of similar questions.

In its decision in *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978), this Court noted that the congressional purpose to supersede the police power of the states may manifest itself through a scheme of federal regulation which is so pervasive that it is reasonable to infer that Congress left no room for the states to supplement it; or may exist where the regulatory field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject; or where the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose as the state ruling; or where a state rule actually conflicts with or stands as an obstacle to the accomplishment of goals embodied in a valid federal statute, and so is void to that extent. 435 U.S. at 158. Consideration of Petitioner's Supremacy Clause argument begins with the recognition that "the historic police powers of the state were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 435 U.S. at 157.

A. Federal Law Has Not Occupied The Field Of Drug Regulation So As To Prevent States From Supplementing The Field.

Although the introduction of new drugs is extensively controlled by the federal government, a long line of United States Supreme Court cases has held that Congress left room for state and municipal regulations in that field. In *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427 (1919), this Court upheld a state statute that supplemented the federal Drug and Cosmetic Act. Furthermore, numerous

cases have recognized state civil remedies for personal injury, death, or property damage resulting to consumers from dangerous drugs. *See, e.g., Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F. Supp. 364, 365-66 (S.D. Fla. 1971), and the cases cited therein. Indeed, the legislative history of the federal Food and Drug Act indicates that the express provision for a private right of action for damages was included in an earlier version of the bill but was omitted from all later versions on the ground that it would create an unnecessary federal action duplicative of state remedies. *Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F. Supp. at 365 n.2, *citing* Hearings on S. 1944, before a Subcommittee of the Commerce Committee, U.S. Senate, 73d Cong., 2d Sess., pp. 10, 144, 219, 403, 431, 444 (1933). The federal scheme of drug regulation is simply not so pervasive as to justify the inference that a state may not supplement it with a rule of civil liability like that found in the *Collins* decision.

Nor does the federal scheme demonstrate a federal interest so dominant that it precludes state regulation of the same subject matter. Unlike some areas such as foreign affairs and immigration, state tort law traditionally has been viewed as within the proper scope of the states' police power. Congress could, of course, choose to federalize product liability law, as has been proposed in the Uniform Product Liability Law, S.44, 98th Cong., 1st Sess. (1983), now pending before Congress. Until such time as Congress chooses to do so, however, it is within the authority of the states to regulate their own tort law.

B. The Collins Decision Does Not Govern The Same Area As That Of The Federal Laws Governing A Drug Manufacturer, Nor Does The Collins Decision Conflict With Any Federal Statute.

A clear and manifest purpose of Congress to supersede the police power of a state may be shown where the object sought to be obtained by the federal government and by the challenged state rule reveal the same purpose. *Southern R. Co.* v. *Railroad Commission,* 236 U.S. 439, 447 (1915).

The *Collins* formulation is not an attempt to achieve the same purposes as the federal Drug and Cosmetic Act, nor does it impose the same obligations as that Act. The federal Act is concerned with the safety and efficacy of prescription drugs. The Act achieves this purpose through labeling, registration, and disclosure requirements. The Act makes no attempt to define or prescribe a drug manufacturer's liability for injuries caused by defective products. *Orthopedic Equipment* v. *Eutsler,* 276 F.2d 455, 460 (4th Cir. 1960).

In contrast, the *Collins* decision is merely a mechanism designed to equitably allocate responsibility for damage caused by a drug manufacturer's defective products. Its only purpose is to compensate innocent DES victims who cannot identify the manufacturer of the DES pills that caused them harm.

Because the federal Act does not purport to govern rules of civil liability arising from defective drugs and the *Collins* decision does not purport to govern labeling, registration, or disclosure requirements for drugs, the *Collins* rule is not preempted as attempting to govern the same area or impose the same obligations as an existing federal law. In this connection, Petitioner appears to make no claim

that the *Collins* decision is in direct conflict with any federal authority. It appears, indeed, that Petitioner could make no such claim.

Nor does Petitioner identify any purpose or objectives of Congress with which the *Collins* decision may conflict. We note, however, that the *Collins* decision *promotes* federal drug policies. The objective of the federal regulatory system is *not* to insulate manufacturers of *defective* products from liability. The purpose of the Food, Drug and Cosmetic Act, 21 U.S.C. §301, is to protect consumers, who in the circumstances of modern industrialism are largely beyond self-protection. *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951). The *Collins* formulation does not impose liability on all manufacturers in the drug industry regardless of fault. It imposes liability *only* when a manufacturer has produced a defective product. It is consistent with, and promotes, federal policy.

Further, the *Collins* decision will not frustrate federal policies favoring the production and marketing of generic drugs. The decision in *Collins* does not assign liability without fault. To be responsible for damages under this rule, a drug manufacturer must produce a defective product. Contrary to Petitioner's arguments, such a rule will more likely serve to further, rather than frustrate, the Congressional objective to protect helpless consumers. Holding drug manufacturers liable for the injuries caused by their products will definitely provide incentives to produce safer drugs.

V.

THE COLLINS DECISION IS NOT A REGULATION AFFECTING INTERSTATE COMMERCE.

The Commerce Clause of the United States Constitution provides that Congress shall have the power "[t]o regulate Commerce . . . among the several States." Article I, Section 8, Clause 3. Petitioner claims that the *Collins* decision contravenes the Commerce Clause by creating an impermissible burden on interstate commerce. However, it is well established that civil remedies—which only "indirectly" relate to or affect interstate commerce—are not "regulations" for purposes of the Commerce Clause.

The constitutionality of civil remedies under the Commerce Clause has been thoroughly treated by this Court in such long-standing precedent as *Missouri, Kansas & Texas R. Co.* v. *Haber,* 169 U.S. 613 (1898), and *Sherlock* v. *Alling,* 93 U.S. 99 (1876). Where state statutes establishing rebuttable presumptions and new rights of action are challenged as impermissible burdens on interstate commerce, this Court has rejected the challenge when it concludes that the statutes do not constitute a regulation within the meaning of the Commerce Clause. Such statutes "only declare a general principle respecting the *liability* of all persons within the jurisdiction of the State *for torts* resulting in the death of parties injured. General legislation of those prescribing the liabilities or duties of citizens of this state without distinction as to pursuit or calling is not open to any valid objection because it may affect persons engaged in foreign or interstate commerce." *Sherlock,* 93 U.S. at 103 (emphasis added).

In a similar vein, the *Haber* decision states:

> "It is said that the statute of Kansas giving a right of action for damages is, in itself, a regulation of

> commerce among the States, and therefore, inconsistent with the power of Congress to regulate such commerce. But that statute is not within the meaning of the Constitution, nor in any just sense, a regulation of commerce among the States. . . . It did nothing more than declare as a *rule of civil liability* in Kansas, that anyone driving, shipping or transporting or causing to be driven, shipped or transported, into or through any county, in that state, cattle liable to impart or capable of communicating Texas, splenic or Spanish fever to domestic cattle should be responsible to any person injured thereby." 169 U.S. at 625 (emphasis added).

In light of *Haber* and *Sherlock*, the *Collins* decision cannot be considered a regulation affecting interstate commerce.[3] The *Collins* decision does not prohibit any commerce among the states. It does nothing more than make drug manufacturers responsible for damage caused by a dangerous product. It simply fashions a rule of civil liability well within the state's inherent power to protect its citizenry. Moreover, the *Collins* decision imposes no tax, proscribes no duty and in no respect interferes with any regulations providing for the manufacture and distribution of drugs. For these reasons, the rule in the *Collins* decision is not prohibited by the Commerce Clause of the federal Constitution.

Petitioner also claims that the mere lack of uniformity among state tort law, which decisions such as *Collins* may

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[3] There are four important similarities between the rule of law in the *Collins* case and the statutes involved in *Haber* and *Sherlock*:

(a) All create or allow causes of action for negligent behavior;

(b) All involve use of rebuttable presumptions;

(c) All were challenged on Commerce Clause grounds;

(d) All did not directly affect interstate commerce.

reflect, is a burden on interstate commerce. In effect, this is an attack on the customary federal-state relationship in the area of personal injury law. The fact that present negligence standards and strict liability standards vary from state-to-state does not mean interstate commerce is impermissibly burdened. Instead, the variations are a testament to the fact that those standards are generally regarded as matters left to the states. If there were *fifty* separate state standards applied in product liability cases, that would merely be due to the legitimate operation of the safeguards for local experimentation embodied in the United States Constitution. While Congress could act to preempt the field, until it does so Petitioner's Commerce Clause arguments simply ask this Court to make a judgment as to which state's personal injury law is best, and in that manner to federalize tort law. Such a judgment would be a dramatic alteration of this Court's role in the federal-state relationship, and would be unwarranted.

Because the *Collins* rule is not a regulation affecting interstate commerce, it is unnecessary to address whether the decision is rationally related to a legitimate state end, whether the regulatory burden imposed on interstate commerce is outweighed by the state's interest, or whether there is a less burdensome alternative to the remedy chosen by the Wisconsin Supreme Court. Even if these issues were relevant, the prior discussion demonstrates that the *Collins* formulation is rationally related to a legitimate state goal, and that the Wisconsin Supreme Court arrived at this decision after carefully weighing all relevant factors.

CONCLUSION

The petition for a writ of certiorari to the Supreme Court of Wisconsin should be denied.

Respectfully submitted,

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APPENDIX

APPENDIX A

EXCERPT OF ENTIRE FEDERAL CONSTITUTIONAL ARGUMENT CONTAINED IN JOINT BRIEF OF PETITIONER AND OTHER DEFENDANT DRUG COMPANIES BEFORE THE WISCONSIN SUPREME COURT

"Because no one can predict the results of such a fundamental policy change as requested by plaintiff, and [sic] such a change is an inappropriate matter for judicial determination. *See also, Judevine* v. *Benzies-Montanye Fuel & Warehouse Co.*, 222 Wis. 512, 527, 269 N.W. 295, 302 (1936), *questioned on other gds.*, 15 Wis.2d 452, 113 N.W.2d 135 (1962); *Yoeckel* v. *Samonig*, 272 Wis. 430, 434, 75 N.W. 2d 925 (1956), also refusing to engage in 'judicial legislation."[25]

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[25] In addition, to adopt alternative or market share liability would result in a denial of both substantive and procedural due process to defendants because these theories create a mandatory presumption of liability without proof that it is more likely than not that defendant's product caused plaintiff's injuries, but rather on the basis that it simply could have done so. *See, Speiser* v. *Randall*, 357 U.S. 513, 523-24 (1958); *Wolff* v. *McDonnell*, 418 U.S. 539, 557-58 (1974). The Equal Protection clause would also be violated, *see Stanley* v. *Illinois*, 405 U.S. 645, 648, 6[illegible]5 (1972), as would the Commerce Clause, *Dean Milk Co.* v. *Madison*, 340 U.S. 349 (1951), and the Supremacy Clause, *see Sola Elec. Co.* v. *Jefferson Elec. Co.*, 317 U.S. 173 (1942), by adopting a theory of liability which erects barriers to commerce, treats generic drug manufacturers differently than other defendants, and frustrates and impedes enforcement of federal law governing prescription drugs."

[Text from page 56 of Joint Brief; footnote from pages 56-57].

APPENDIX B

LAW REVIEW ARTICLES ADDRESSING THE DES CAUSATION PROBLEM

1983:

Fischer, *Tort Law: Expanding the Scope of Recovery Without Loss of Jury Control,* 11 Hofstra L. Rev. 937 (1983).

Hirsch, *Bichler and Sindell: Generic Drug Products and Liability Without Causation,* 33 Fed'n Ins. Coun. Q. 315 (1983).

Seltzer, *Punitive Damages in Mass Tort Litigation: Addressing the Problem of Fairness, Efficiency and Control,* 52 Fordham L. Rev. 37 (1983).

Comment, *Beyond the Dalkon Shield: Proving Causation Against IUD Manufacturers for PID Related Injury,* 13 Golden Gate L. Rev. 639 (1983).

Comment, *Market Share Liability for Injurious Products: A Comment on Sindell,* 41 U. Toronto Fac. L. Rev. 52 (1983).

McGovern, *Management of Multiparty Toxic Tort Litigation: Case Law and Trends Affecting Case Management,* 19 Forum 1 (1983).

Comment, *Punitive Damages in DES Market Share Litigation,* 23 Santa Clara L. Rev. 185 (1983).

Downey, *Theories of Recovery for DES Damage: Is Tort Liability the Answer?,* 4 J. Legal Med. 167 (1983).

Roberts, *DES and the Identification Problem,* 16 Akron L. Rev. 447 (1983).

Endress, *Market Share Liability: A One Theory Approach Beyond DES,* 1983 Det. C.L. Rev. 1.

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Delgado, *Beyond Sindell: Relaxation of Cause-In-Fact Rules for Indeterminate Plaintiffs,* 70 Calif. L. Rev. 881 (1982).

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Brennan, *DES: The Patchwork Quilt of Tort Law,* 2 N. Ill. U.L. Rev. 369 (1982).

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Ciemiega, *DES: Alternative Theories of Liability,* 59 U. Det. J. Urb. L. 387 (1982).

Kinard, *Causation-in-Fact—DES Lawsuits,* 34 S.C.L. Rev. 222 (1982).

McGoldrick, *Products Liability—Recent Developments in "DES Daughters" Cases,* 31 Def. L.J. 245 (1982).

Parlee, *Overcoming the Identification Burden in DES Litigation: The Market Share Liability Theory,* 65 Marq. L. Rev. 609 (1982).

Abrahams, *The DES Labyrinth,* 33 S.C.L. Rev. 663 (1982).

Carter, *The DES Dilemma: An Analysis of Recent Decisions,* 52 Miss. L.J. 199 (1982).

Reed, *The DES Cases and Liability Without Causation,* 19 Am. Bus. L.J. 511 (1982).

Bryan, *Current Problems, Tools and Theories in Multi-Party Products Liability Cases,* 18 Forum 117 (1982).

1981:

King, *Causation, Valuation, and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences,* 90 Yale L.J. 1353 (1981).

Note, *Industry-Wide Liability: Solving the Mystery of the Missing Manufacturers in Products Liability Law,* 38 Wash. & Lee L. Rev. 139 (1981).

Fischer, *Products Liability—An Analysis of Market Share Liability,* 34 Vand. L. Rev. 1623 (1981).

Note, *Products Liability: Sindell* v. *Abbott Laboratories: Proportional Unidentified Fairness and the Oklahoma Perspective,* 34 Okla. L. Rev. 843 (1981).

Note, *Market Share Liability Adopted to Overcome Defendant Identification Requirement in DES Litigation,* 59 Wash. U.L.Q. 571 (1981).

Eimert, *DES: Judicial Interest Balancing and Innovation,* 22 B.C.L. Rev. 747 (1981).

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Note, *DES Cases and the Move Toward New Tort Remedies*, 49 U.Mo.K.C.L. Rev. 245 (1981).

Note, *A New Avenue for DES Litigation*, 11 Golden Gate U.L. Rev. 917 (1981).

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Note, *Products Liability—Theories of Alternative and Enterprise Liability Held Inapplicable in DES Cases Absent Legislative Imprimatur*, 12 Seton Hall L. Rev. 179 (1981).

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Note, *Market Share Liability and DES: Square Pegs in Round Holes*, 13 Conn. L. Rev. 777 (1981).

Turner, *Bearing the Burden of DES Exposure*, 60 Or. L. Rev. 309 (1981).

Norris, *Product Quality and Safety—Manufacturers Liability—DES*, 7 Am. J.L. & Med. 213 (1981).

Note, *Tort—An Injured Plaintiff May Maintain an Action for Damages Against a Substantial Percentage of the Manufacturers of Diethystilbestrol (DES) Even Though She is Unable to Identify the Particular Manufacturer of the Drug Her Mother Ingested*, 19 J. Fam. L. 544 (1981).

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Mudano, *Market Share Liability—A New Theory for DES Cases,* 4 Am. J. Trial Advoc. 492 (1980).

Silbersweig, *An Analysis of the Massachusetts DES Class Action Suit,* 6 Am. J.L. & Med. 243 (1980).

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Note, *Manufacturers Liability Based on a Market Share Theory: Sindell* v. *Abbott Laboratories,* 16 Tulsa L.J. 286 (1980).

Note, *Torts—Products Liability—Joint Liability—An Individual Manufacturer of a Drug Produced Industry-Wide From An Identical Formula is Liable For Injuries in Proportion to its Share of the Products Market if the Particular Injury-Causing Product's Manufacturer Cannot Be Identified and The Named Defendants Produced a Substantial Market Share of the Drug,* 49 U. Cin. L. Rev. 926 (1980).

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Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L. Rev. 963 (1978).

Note, *Market Share Liability: A New Method of Recovery for DES Litigants*, 30 Cath. U.L. Rev. 551 (1978).

Note, *Proof of Causation in Multiparty Drug Litigation*, 56 Tex. L. Rev. 125 (1977).

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